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VIA ECF

Honorable Stanley R. Chesler, U.S.D.J.
United States District Court
District of New Jersey
50 Walnut Street
Newark, New Jersey 07102

**RE: Takeda Pharmaceutical Co. Ltd. *et al.* v. Norwich Pharmaceuticals, Inc.,
Civil Action No. 2:20-cv-08966 (SRC)(CLW)**

Dear Judge Chesler,

Our firm, together with Haug Partners LLP, represents Plaintiffs Takeda Pharmaceutical Co. Ltd. and Takeda Pharmaceuticals Inc. (“Takeda”). We write regarding the Federal Circuit’s recent decision in *Kyocera Senco Indus. Tools Inc. v. ITC*, Nos. 2020-1046, -2050 (Fed. Cir. Jan. 21, 2022). (Attached as Exhibit A). The *Kyocera* decision is supplemental authority supporting Takeda’s claim construction argument concerning the level of ordinary skill in the art (*see* ECF No. 112 at 2-5).

In a precedential decision, the Federal Circuit found that an ALJ abused his discretion by “admitting any” testimony from an expert witness who “lacked ordinary skill in the art.” *Kyocera*, No. 2020-1046, -2050, slip op. at 9-11 (emphasis added). There, during claim construction, the ALJ adopted a definition of a skilled artisan requiring, *inter alia*, “two years’ experience designing power nailers.” *Id.* at 9. But appellant *Kyocera*’s proffered expert lacked experience in power nailer design. *Id.* at 10. As the Federal Circuit explained:

To offer expert testimony from the perspective of a skilled artisan in a patent case—like for claim construction, validity, or infringement—a witness must at least have ordinary skill in the art. Without that skill, the witness’ opinions are neither relevant nor reliable.

Id. at 11 (emphasis added). Thus, the Court ruled that it was an abuse of discretion to “admit[] [the expert’s] testimony on any issue that is analyzed through the lens of an ordinarily skilled artisan.” *Id.* at 12-13.

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The *Kyocera* decision supports Takeda's assertion that Norwich's experts "lack [any] relevant experience" to support Norwich's definition of a skilled artisan. (ECF No. 112 at 4). If the Court adopts Norwich's proposed level of skill in the art, the testimony of **both** of Norwich's experts, Dr. Hollingsworth and Dr. Barzman, should be excluded because each lacks the experience of Norwich's proposed POSA. (See ECF No. 112 at 3-4).

Norwich contends that the POSA has "two years of experience in drug discovery and formulation, including in the development of potential drug candidates." (*Id.* at 2 (emphasis omitted)). However, Dr. Hollingsworth has never "done work in drug formulation" and never "done work in drug discovery" outside his litigation work. (*Id.* at 3). Similarly, Dr. Barzman has no experience in "drug discovery," "drug formulation," or "the development of potential drug candidates." (*Id.*)¹ Because claim construction is analyzed from the perspective of a person of ordinary skill in the art (see ECF No. 88 at 4 (citing *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (en banc))), if Norwich's proposed level of skill is adopted, the testimony of Norwich's experts should be excluded as "neither relevant nor reliable." See *Kyocera*, No. 2020-1046, -2050, slip op. at 11.

Takeda maintains that the Court should adopt Takeda's proposed level of ordinary skill in the art. However, as in *Kyocera*, if the Court adopts Norwich's definition, the testimony of Norwich's experts—who admit that they do not possess at least ordinary skill in the art—should be excluded. See *id.*

Respectfully submitted,

s/ Michael R. Griffinger
Michael R. Griffinger

Attachment
Cc: All counsel of record

¹ Norwich's proposed level of skill also supposes that the ordinarily skilled artisan would consult with others having, e.g., an M.D. and the requisite experience. ECF No. 112 at 2. Dr. Barzman opined that the requisite experience includes assessing the "variability in [a] study dose." *Id.* at 4. But Dr. Barzman—who has never assessed the variability in a study dose—does not even possess the experience of the supposed consultant to the POSA.